Claims

1. A method of determining an analyte in a sample comprising the steps of:

a) contacting the sample with a specified amount of a receptor which binds specifically to the analyte to form an analyte/receptor complex, said specified amount of receptor being in excess of that required to bind all analyte in the sample,

b) isolating on a solid phase a specified fraction of the amount of receptor contacted with the analyte, including analyte/receptor complex and unreacted receptor,

c) detecting the amount of analyte/receptor complex in said isolated specified fraction, and

d) from the detected amount analyte/receptor complex, determining the concentration of analyte in the sample.

2. The method according to claim 1 in which the sample has a high concentration.

3. The method according to claim 1 or claim 2 in which the sample is undiluted.

4. The method according to claims 1 to 3, wherein isolating said specified fraction of the amount of receptor contacted with the sample on the solid phase comprises providing a solid phase having binding sites for the receptor, and after contacting the sample, or an aliquot thereof, with a liquid phase containing the receptor, binding said specified fraction of receptor to the solid phase.

5. The method according to claim 4, wherein the whole amount of receptor has reactivity towards said binding sites on the solid phase, and the receptor-binding

capacity of the solid phase is less than the solid-phase-binding capacity of receptor contacted with the sample.

6. The method according to claim 4, wherein only a specified fraction of the amount of receptor contacted with the sample has reactivity towards said binding sites on the solid phase.

7. The method according to claims 1 to 3, wherein isolating said specified fraction of the amount of receptor on the solid phase comprises contacting the sample with a specified amount of receptor, a specified fraction of which amount is immobilized to said solid phase and the remaining amount of receptor being in a liquid phase.

8. The method according to any one of claims 1 to 6, wherein the receptor comprises a first part that binds specifically to the analyte, and a second part that binds to the solid phase.

9. The method according to claim 8, wherein the solid phase binding part of the receptor comprises one member of a specific binding pair, and the other member of the binding pair is immobilized to the solid phase.

10. The method according to any one the preceding of claims, wherein in step c) the analyte/receptor complex is detected by a labelled detection reagent which binds specifically to the analyte.

11. The method according to any one of the preceding claims, wherein the ratio between said isolated fraction of the amount of active analyte-binding receptor and the total amount of active analyte-binding receptor contacted with the sample is in the range

of from about 1:2 to about 1:1000, preferably from about 1:5 to about 1:100, particularly no more than about 1:20.

12. The method according to any one of the preceding claims, wherein said solid phase binding sites for the receptor are immobilized in a reaction zone of a flow matrix, preferably a lateral flow matrix, such as a membrane strip.

13. The method according to any one of the preceding claims, wherein the receptor is an antibody or an immunoactive fragment thereof.

14. The method according to any one of the preceding claims, wherein the detection reagent is an antibody or an immunoactive fragment thereof.

15. The method according to any one of the preceding claims, wherein the detection reagent is labelled by a fluorophore or a chromophore.

16. The method according to any one of the preceding claims, wherein the specific binding pair is biotin-avidin or biotin-streptavidin.

17. The method according to any one of the preceding claims, wherein the sample is an undiluted serum sample.

18. The method according to any one of claims 1 to 16, wherein the sample is an undiluted whole blood sample.

19. A test kit for determining an analyte in a sample, comprising a specified amount of a receptor substance having a first part which binds specifically to the analyte, and a solid phase member having immobilized thereon a ligand which binds specifically to a second part of the receptor, the receptor-binding capacity of said ligand on the solid phase member being less than the ligand-binding capacity of said specified amount of receptor substance.

20. The test kit according to claim 19, wherein the ratio between the receptor-binding capacity of ligand immobilized on the solid phase and the ligand-binding capacity of the analyte-specific receptor substance is in the range of from about 1:2 to about 1:1000, preferably from about 1:5 to about 1:100, particularly no more than about 1:20.

21. The test kit according to claim 19 or 20, comprising a lateral flow membrane strip having said receptor-binding ligand immobilized in or on a reaction zone of the membrane and having said analyte-binding receptor substance dissolvably pre-deposited in or on the membrane upstream of the reaction zone.

22. A test kit for determining an analyte in a sample, comprising a specified amount of a receptor substance having a first part which binds specifically to the analyte, only a specified fraction of the amount of receptor substance having a second part capable of binding to a specific ligand, and a solid phase member having said specific ligand immobilized thereon.

23. The test kit according to claim 22, wherein the ratio between the amount of ligand-binding analyte-specific receptor and the total amount of analyte-specific receptor is in the range of from about 1:2 to about 1:1000, preferably from about 1:5 to about 1:100, particularly no more than about 1:20.

24. The test kit according to claim 22 or 23, comprising a lateral flow membrane strip having said receptor-binding ligand immobilized in or on a reaction zone of the membrane and having said analyte-binding receptor substance dissolvably pre-deposited in or on the membrane upstream of the reaction zone.

25. A test kit for determining an analyte in a sample, comprising a first specified amount of an analyte-binding receptor substance, and a solid phase member having immobilized thereon a second specified amount of said analyte-binding receptor substance.

26. The test kit according to claim 25, wherein the ratio between said second amount of analyte-binding receptor substance immobilized to the solid phase, and the sum of said first and second amounts of analyte-binding receptor substance is in the range of from about 1:2 to about 1:1000, preferably from about 1:5 to about 1:100, particularly no more than about 1:20.

27. The test kit according to claim 25 or 26, comprising a lateral flow membrane strip having said second amount of analyte-binding receptor immobilized in or on a reaction zone of the membrane and having said first amount of analyte-binding receptor dissolvably pre-deposited in or on the membrane upstream of the reaction zone.

28. The test kit according to claim 25 or 26, comprising a solid phase well having said second amount of analyte binding receptor immobilized therein and having said first amount of analyte-binding receptor dissolvably pre-deposited in the well or in close contact with the well.